



SERIAL NO. 09/933,708
ATTY. NO.: 54719.000028

TECH CENTER 1600/2900

MAR 27 2003

RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas PICCARIELLO et al

Serial Number: 09/933,708

Filed: August 22, 2001

For: ACTIVE AGENT DELIVERY SYSTEMS AND METHODS FOR PROTECTING
AND ADMINISTERING ACTIVE AGENTS

Group Art Unit: 1653

Examiner: Unassigned

INFORMATION DISCLOSURE STATEMENT

Director of the Patent and Trademark Office
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants are submitting herewith copies of the references listed on the attached Form PTO/SB/08A for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form PTO/SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

Applicants' submission of the Information Disclosure Statement shall not be construed as an admission that the cited references are prior art to the present invention, or that the cited references qualify as printed publications. The submission of this IDS also shall not be construed as a representation that a prior art search has been performed.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is submitted prior to issuance of a first Office Action. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.



21967

PATENT TRADEMARK OFFICE

Respectfully submitted,

HUNTON & WILLIAMS

Dated: March 26, 2003

By: 

Jeffrey T. Perez
Registration No. 52,110

HUNTON & WILLIAMS
1900 K Street, N.W., Suite 800
Washington, DC 20006-1109
Tel: (202) 955-1500
Fax: (202) 778-2201

→ $\boxed{+}$

31 +

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

(use as many sheets as necessary)

1

of

5

09/933.708

August 22, 2001

Thomas PICCARIELLO et al.

1653

Unassigned

54719.000028

RECEIVED
MAR 27 2003
U.S. DEPT. OF COMMERCE
INTELLIGENCE & TRADEMARK OFFICE
MAR 26 2003
TECH CENTER 160/2900
Relevant

Releva 160/2900

27 2003

Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 5

Complete if Known

Application Number 09/642,820
Filing Date August 22, 2000
First Named Inventor Thomas PICCARIELLO et al.
Group Art Unit 1653
Examiner Name Jeffrey E. RUSSEL
Attorney Docket Number 54719.000016



OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	P49	CANARIS, G., "The Colorado Thyroid Disease Prevalence Study," Archives Internal Medicine Articles and Abstracts, Vol. 160, No. 4 (2000).	
	P50	BUNEVICIUS, R., "Effects of Thyroxine as Compared with Thyroxine Plus Triiodothyronine in Patients with Hypothyroidism," The New England Journal of Medicine, Vol. 340, No. 6 (1999).	
	P51	TOFT, A., "Thyroid Hormone Replacement -- One Hormone or Two?," The New England Journal of Medicine, Vol. 340, No. 6 (1999).	
	P52	PADE, V., et al., "Link Between Drug Absorption Solubility and Permeability Measurements in Caco-2 Cells," Journal of Pharmaceutical Sciences, Vol. 87, No. 12 (1998).	
	P53	OH, D., et al., "Estimating the Fraction Dose Absorbed from Suspensions of Poorly Soluble Compounds in Humans: A Mathematical Model," Pharmaceutical Research, Vol. 10, No. 2 (1993).	
	P54	AMIDON, G., et al., "A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of in Vitro Drug Product Dissolution and in Vivo Bioavailability," Pharmaceutical Research, Vol. 12, No. 3 (1995).	
	P55	Presentation to Knoll Pharmaceutical, April 10, 2000.	
	P56	Investment Banking Presentation, March 27-31, 2000	
	P57	Pharma Presentation, March 27-31, 2000, New York, NY.	
	P58	Deutsche Banc Alex Brown 2000 Health Care Conference Presentation, May 10, 2000, Baltimore, MD.	
	P59	April 7, 2000, Letter to Credit Suisse First Boston Corporation	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 5

Complete if Known

Application Number	09/642,820
Filing Date	August 22, 2000
First Named Inventor	Thomas PICCARIELLO et al.
Group Art Unit	1653
Examiner Name	Jeffrey E. RUSSEL
Attorney Docket Number	54719.000016



RECEIVED

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	P60	April 7, 2000, Letter to Chase, Hambrecht and Quist	
	P61	April 7, 2000, Letter to Banc of America Securities, LLC	
	P62	April 7, 2000, Letter to Johnson & Johnson	
	P63	April 7, 2000, Letter to AstraZeneca LP	
	P64	April 7, 2000, Letters to Bear, Stearns & Company, Inc.	
	P65	Bankers Presentation, March 27-31, 2000	
	P66	Pharmaceutical Presentation, March 27-31, 2000	
	P67	KPMG Auditors' Report, March 12, 1999	
	P68	Final Report, Study Completion Date June 25, 1998	
	P69	Investment Banking Presentation, March 27-31, 2000	
	P70	Pharmaceutical Presentation, March 27-31, 2000	

Examiner
Signature

Date
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box



PTO/SB/08A (08-00)



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

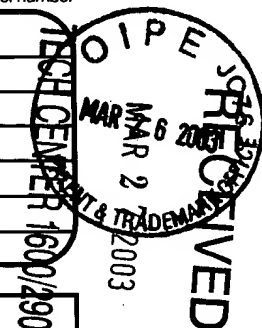
INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 5

Complete if Known

Application Number	09/642,820
Filing Date	August 22, 2000
First Named Inventor	Thomas PICCARIELLO et al.
Group Art Unit	1653
Examiner Name	Jeffrey E. RUSSEL
Attorney Docket Number	54719.000016



OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	P71	Deutsche Banc Alex Brown 2000 Health Care Conference Presentation, May 10, 2000, Baltimore, MD.	
	P72	Investment Banking (short) Presentation, April 27, 2000	
	P73	Investment Banking (long) Presentation, April 27, 2000	
	P74	Banc of America Presentation	
	P75	Pharma Presentation, April 2000	
	P76	AstraZeneca Presentation	
	P77	"Promise of Polythroid," Presentation, March 2000	
	P78	"Introducing Polythroid," Presentation, March 2000	
	P79	Investment Banking Presentation	
	P80	Pharma Presentation, March-April	
	P81	Deutsche Banc Alex Brown 2000	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 5 of 5

Complete if Known

Application Number	09/642,820
Filing Date	August 22, 2000
First Named Inventor	Thomas PICCARIELLO et al.
Group Art Unit	1653
Examiner Name	Jeffrey E. RUSSEL
Attorney Docket Number	54719.000016

TECHNICAL CENTER 1600/2900



OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	P82	August 31, 1999 Presentation to Scios, Inc.	
	P83	February 2000 Presentation to Andrx	
	P84	March 15, 2000 Presentation to BASF	
	P85	Original Presentation to BASF	
	P86	February 10, 2000 Lotus Presentation	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.